

Notice of Allowability

Application No.

09/699,136

Applicant(s)

SANTI ET AL.

Examiner

Kathleen M. Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/18/05.
2. ☒ The allowed claim(s) is/are 1,17,24,26-39,41 and 42.
3. ☒ The drawings filed on 27 October 2000 and 25 August 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Kathleen M Kerr
Primary Examiner
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DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on November 26, 2003), Applicants filed responses and amendments received on May 28, 2004 (substitute specification, non-compliant claims), September 27, 2004, and January 18, 2005 (sequence listing). The amendment filed on September 27, 2004 amended Claims 1, 24, 28, 29, 32-43, 36, and 37. Thus, Claims 1, 17, 24, and 26-39 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/161,703 filed on October 27, 1999.

Drawings

3. The drawings have been approved by the Draftsman and are considered acceptable for publication upon allowance.

Compliance with the Sequence Rules

4. A new sequence listing, in computer readable form and paper copy, was filed on January 18, 2005; said listing has been entered.

Withdrawn - Objections to the Specification

5. Previous objection to the amendment filed August 25, 2003 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of Applicant's amendment to the sequence listing.
6. Previous objection to the specification for inappropriate notation of an Internet address is withdrawn by virtue of Applicant's amendment deleting the notation.
7. Previous objection to the specification for having inconsistent and/or unclear reference citations is withdrawn by virtue of Applicant's amendment in the substitute specification. The Examiner notes that all amendments are clearly support by references in the specification except for two. Ziermann *et al.* (see new paragraph [0174]), which was previously cited with two authors, a full title, a journal (J. Bacteriol.), and a publication year (1998), is evident as amended despite a new journal (J. Ind. Microbiol. Biotech.) and new publication year (2000) because the citation, as amended, was able to be found by the Examiner using only the information provided in the original filing. Leadlay *et al.* (see new paragraph [0151], which was previously cited as only "Leadlay *et al.* (1981)" is supported as amended because the citations was able to be found using just the author and publication year. No new matter has been added.
8. Previous objection to the specification for being unclear is withdrawn by virtue of Applicant's amendments in the substitute specification.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 1, 17, 24, and 26-39 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicant's amendment removing references to SEQ ID NOs:1-4 as altered previously.

10. Previous rejection of Claims 1, 17, and 26-35 under 35 U.S.C. § 112, second paragraph, as being indefinite for the claim language "said PKS gene being contained in a vector that replicates extrachromosomally or is integrated into the chromosomal DNA of such a host cell" is withdrawn by virtue of Applicant's amendment.

11. Previous rejection of Claims 1, 17, and 26-35 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "wherein the products of said methylmalonyl CoA mutase and said epimerase genes are effective" is withdrawn by virtue of Applicant's amendment.

12. Previous rejection of Claim 34 under 35 U.S.C. § 112, second paragraph, as being indefinite for, at the end of the claim "or a gene", is withdrawn by virtue of Applicant's cancellation of said phrase.

EXAMINER'S AMENDMENT

13. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Gary Ashley on May 4, 2005.

Amendments to the Claims

14. The claims have been amended as follows:

a) Rewrite Claim 1 as follows:

---1. A recombinant *E. coli* host cell comprising one or more expression vectors, said expression vectors comprising alone or in combination:

- a) methylmalonyl CoA mutase genes mutA and mutB from either *Propionibacterium shermanii* or *Streptomyces cinnamonensis*,
- b) the epimerase gene from *Propionibacterium shermanii* having the nucleotide sequence given in SEQ ID NO: 1, and
- c) at least one modular polyketide synthase (PKS) gene,

wherein the proteins encoded by said methylmalonyl CoA mutase and epimerase genes are effective to produce S-methylmalonyl CoA, which is a substrate required for biosynthesis of a polyketide produced by said modular PKS produced,

said PKS gene being contained in a vector that replicates extrachromosomally or is integrated into chromosomal DNA of such host cell, wherein said host cell, in the absence of said expression vectors, is unable to make said polyketide.---

b) Rewrite Claim 24 as follows:

---24. An *E. coli* host cell that expresses

- a) methylmalonyl CoA mutase genes *mutA* and *mutB* from either *Propionibacterium shermanii* or *Streptomyces cinnamonensis*,
- b) the epimerase gene from *Propionibacterium shermanii* having the nucleotide sequence given in SEQ ID NO: 1, and
- c) at least one modular polyketide synthase (PKS) gene,

wherein said PKS gene or genes are contained in a vector that replicates extrachromosomally or is integrated into chromosomal DNA.---

c) Add new Claims 41-42.

---41. A method for producing a polyketide, which method comprises culturing the host cell of Claim 1 or 24 under conditions such that

said PKS gene is expressed to produce a functional PKS,

said methylmalonyl CoA is produced and

said functional PKS synthesizes a polyketide that incorporates said S-methylmalonyl CoA.

42. The method of Claim 41, wherein the host cell is cultured in a medium that contains hydroxocobalamin.---

Conclusion

15. Claims 1, 17, 24, 26-39 and 41-42 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

May 5, 2005